

### ENZYMATIC THERADY

INCORPORATED What Better feels like."

TEGRATIVE THERAPEUTICS INC." NF Formulas + PhytoPharmica

Tyler Encapsulations \* Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 + F: 503.582.0467

# **PHYTOPHARMICA**

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 • F: 888.570.6460 (Enzymatic) P: 920.469.9099, • F: 920.469.4418 (Phyto)

April 26, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH
Body Rewards	Carb Defense taken before any meal containing a	White Kidney Bean
Carb Defense™*	starch carbohydrate (pasta, bread, potatoes, grain)	(Phaseolus vulgaris) Extract
	blocks the absorption of starch by inhibiting the	100:1
	digestive enzyme that converts starch to glucose.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Robert Doster

Title: Senior Vice President of Scientific Affairs

4.30-04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely.

Chief Financial Officer

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825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

April 28, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards	White kidney bean extract (Phaseolus vulgaris)	White Kidney Bean (Phaseolus
Carb Defense™*	has been shown in scientific studies to inhibit the enzyme amylase, making it a natural choice for anyone with a low-carb lifestyle, or anyone simply wanting more carbohydrate control.*	vulgaris) Extract 100:1

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	filest
-	Robert Doster Senior Vice President of Scientific Affairs
Date:	4/28/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux
Chief Financial Officer